



PTO/SB/08a (08-03)

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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 1

Complete if Known	
Application Number	10/635,428
Filing Date	August 6, 2003
First Named Inventor	Balaji Venkataraman
Art Unit	1615
Examiner Name	Thurman K. Page
Attorney Docket Number	52761-0100 (285976)

U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

Examiner Signature	E. Peake	Date Considered	3/16/05
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Substitute for Form 1449/A/PTO		Complete if Known		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <small>(use as many sheets as necessary)</small>		Application Number	10/635,428	
		Filing Date	August 6, 2003	
		First Named Inventor	VENKATARAMAN	
		Group Art Unit	1615	
		Examiner Name	Unassigned	
Sheet	1	of 1	Attorney Docket Number	52761-0100 (285976)

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		Group Art Unit	1615
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				Group Art Unit	
				Examiner Name	
Sheet	1	of	6	Attorney Docket Number	52761/285976

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code ² (if known)		
GR	1.	5,494,678		Paradissis, et al.	02-27-1996
GR	2.	5,563,126		Allen, et al.	10-08-1996
GR	3.	5,795,873		Allen	08-18-1998
GR	4.	5,801,161		Merkus	09-01-1998
GR	5.	5,932,624		Herbert	08-03-1999
GR	6.	5,962,048		Register	10-05-1999
GR	7.	6,039,978		Bangs, et al.	03-21-2000
GR	8.	6,048,846		Cochran	04-11-2000
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GR	11.	6,207,651	B1	Allen, et al.	03-27-2001
GR	12.	6,299,896	B1	Cooper, et al.	10-09-2001
GR	13.	6,323,188	B1	Weissman	11-27-2001
GR	14.	6,361,800	B1	Cooper, et al.	03-26-2002
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GR	21.	2003/0049352	A1	Mehansho, et al.	03-13-2003
GR	22.	2003/017136	A1	Cruz, et al. (Abstract)	01-23-2003

FOREIGN PATENT DOCUMENTS					
Examiner Initials	Cite No. ¹	Foreign Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Office ³	Number ⁴		
			Kind Code ⁵ (if known)		
GR	23.	EP	0366480 (Abstract)	B1 Bar Ilan University	08-24-1994
GR	24.	WO	96/11009 (Abstract)	A1 UK	04-18-1996
GR	25.	WO	98/01157 (Abstract)	A1 WWK Trust, Worsley, Andrew Peter	01-15-1998
GR	26.	WO	2000/056295 (Abstract)	A2 Kilgowan Limited	09-28-2000
GR	27.	WO	2001/056609 (Abstract)	A1 Germany	08-09-2001
GR	28.	WO	2002/087593 (Abstract)	A1 Cobalz Limited	11-07-2002

Examiner Signature	G. Reiter	Date Considered	3/16/05
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Sheet	2	of	6	Attorney Docket Number	52761/285976
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OTHER INFORMATION - NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
✓	29.	ALTURA, BURTON M. and ALTURA, BELLA T., "Magnesium and Cardiovascular Biology: An Important Link Between Cardiovascular Risk Factors and Atherogenesis," Cellular and Molecular Biology Research, 1995, pp. 347-359, Vol. 41, No. 5.	
✓	30.	ANDERSSON, H.C., et al., "Long-Term Outcome in Treated Combined Methylmalonic Acidemia and Homocystinemia," Genet Med, May-June 1999, pp. 146-150. (Abstract)	
✓	31.	APPEL, LAWRENCE, J., et al., "A Clinical Trial of the Effects of Dietary Patterns on Blood Pressure," N. Engl. J. Med, April 17, 1997, pp. 1117-1124, Vol. 336, No. 16.	
✓	32.	BASU, TAPAN K. and MANN, SARABJIT, "Vitamin B-6 Normalizes the Altered Sulfur Amino Acid Status of Rats Fed Diets Containing Pharmacological Levels of Niacin Without Reducing Niacin's Hypolipidemic Effects," J. Nutr., 1997, pp.117-121, Vol. 127.	
✓	33.	BLOOM, O. JOSH, et al., "Do Antioxidants (Vitamins C, E) Improve Outcomes in Patients With Coronary Artery Disease?" J. Fam. Prac., November 2002, p. 978, Vol. 51, No. 11.	
✓	34.	BLUMBERG, A., et al., "Vitamin Nutrition in Patients on Continuous Ambulatory Peritoneal Dialysis (CAPD)," Clin Nephrol, November 1983, pp. 244-250, Vol. 20, No. 5. (Abstract)	
✓	35.	BOUSHY, CAROL J., et al., "A Quantitative Assessment of Plasma Homocysteine as a Risk Factor for Vascular Disease," JAMA, October 4, 1995, pp. 1049-1057, Vol. 274, No. 13.	
✓	36.	BRATTSTROM, L. E., et al., "Folic Acid – An Innocuous Means to Reduce Plasma Homocysteine," Scand J. Clin. Lab Invest., 1998, pp. 215-221, Vol. 48.	
✓	37.	BRATTSTROM, LARS E., et al., "Folic Acid Responsive Postmenopausal Homocysteinemia, Metabolism," November 1985, pp. 1073-1077, Vol. 34, No. 11.	
✓	38.	BRATTSTROM, LARS, et al., "Impaired Homocysteine Metabolism in Early-Onset Cerebral and Peripheral Occlusive Arterial Disease," Atherosclerosis, 1990, pp. 51-60, Vol. 81.	
✓	39.	CAMPBELL, BRUCE G., et al., "Do Calcium Supplements Prevent Postmenopausal Osteoporotic Fractures?" J of Fam Prac., March 2003, pp. 236-237, Vol. 52, No. 3.	
✓	40.	CHAMBERS, JOHN C., et al., "Improved Vascular Endothelial Function After Oral B Vitamins," Circulation, Nov. 14, 2000, pp. 2479-2483, Vol. 102.	

Examiner Signature	<i>L. Reh</i>	Date Considered	3/16/05
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet

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of 6

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Application Number	10/635,428
Filing Date	August 6, 2003
First Name of Inventor	Venkataaraman
Group Art Unit	
Examiner Name	
Attorney Docket Number	52761/285976

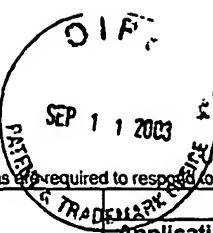
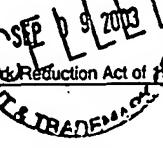
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✓	41.	CHAN, P., et al., "Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of Vitamin B Complex in the Treatment of Nocturnal Leg Cramps in Elderly Patients with Hypertension," J Clin Pharmacol., 1998, pp. 1151-1154, Vol. 38, No. 12. (Abstract)	
✓	42.	DOSHI, SAGAR N., et al., "Folic Acid Improves Endothelial Function in Coronary Artery Disease via Mechanisms Largely Independent of Homocysteine Lowering," Circulation, January 1/8, 2002, pp. 23-26, Vol. 102.	
✓	43.	DUDMAN, NICHOLAS P. B., et al., "Homocysteinemia: Depressed Plasma Serine Levels," Metabolism, February 1987, pp. 198-201, Vol. 36, No. 2.	
✓	44.	ELIAN, et al., "Hydroxocobalamin Reduces Hyperhomocysteinemia in End-Stage Renal Disease," Metabolism, July 2002, pp. 881-886, Vol. 51. (Abstract)	
✓	45.	FANG, JAMES C., et al., "Effect of Vitamins C and E on Progression of Transplant-Associated Arteriosclerosis: A Randomised Trial," The Lancet, March 30, 2002, pp. 1108-1113, Vol. 359.	
✓	46.	FRANKEN, D.G., et al., "Effect of Various Regimens of Vitamin B ₆ , and Folic Acid on Mild Hyperhomocysteinaemia in Vascular Patients," J. Inher. Metab. Dis., 1994, pp. 159-162, Vol. 17.	
✓	47.	GABY, A. R., "Intravenous Nutrient Therapy: The Myers' Cocktail," Altern Med Rev, Oct. 2002, pp. 389-403.	
✓	48.	GARG, REKKA, et al., "Niacin Treatment Increases Plasma Homocyst(e)ine Levels," Am Heart J., December 1999, pp 1082-1087, Vol. 138, No.6, Part 1.	
✓	49.	GOTTFRIES, C. G., "Pharmacological Treatment Strategies in Alzheimer Type Dementia," Eur Neuropsychopharmacol, Nov. 1990, pp. 1-5. (Abstract)	
✓	50.	Hайдари, МЕХРАН, et al., "Enhanced Susceptibility to Oxidation and Diminished Vitamin E Content of LDL from Patients with Stable Coronary Artery Disease," Clinical Chemistry, 2001, pp. 1234-1240, Vol. 47, No.7.	
✓	51.	HARPEY, JEAN-PAUL, et al., "Homocystinuria Caused by 5,10-Methylenetetrahydrofolate Reductase Deficiency: A Case in an Infant Responding to Methionine, Folinic Acid, Pyridoxine, and Vitamin B ₁₂ Therapy," J Pediatrics, February 1981, pp. 275-278, Vol. 98, No. 2.	

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Sheet 4 of 6

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Application Number	10/635,428
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First Name of Inventor	Venkataraman
Group Art Unit	
Examiner Name	

Attorney Docket Number 52761/285976

OTHER INFORMATION - NON PATENT LITERATURE DOCUMENTS

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S	52.	HEINECKE, JAY W., "Is the Emperor Wearing Clothes?" Arterioscler Thromb Vasc Biol., August 2001, pp. 1261-1264, Vol. 21.	
S	53.	HEINONEN, O.P., et al., "The Effect of Vitamin E and Beta Carotene on the Incidence of Lung Cancer and Other Cancers in Male Smokers," TN Engl J Med, April 14, 1994, pp. 1029-1035, Vol. 330, No. 15.	
S	54.	HENKIN, YAAKOV, et al., "Niacin Revisited: Clinical Observations on an Important But Underutilized Drug," Am J Med, September 1991, pp. 239-246, Vol. 91.	
S	55.	HERBERT, V., "The Inhibition and Promotion of Cancers by Folic Acid, Vitamin B ₁₂ , and their Antagonists," American Chemical Society (ACS Symposium series), 1985, pp. 32-36, Vol. 277.	
G	56.	KAUL, NALINI, et al., "α-Tocopherol and Atherosclerosis," E.B.M., 2001, pp. 5-12, Vol. 226.	
S	57.	KLERK, M., "Effect of Homocysteine Reduction by B-Vitamin Supplementation on Markers of Clotting Activation," Thromb Haemost, Aug. 2002, pp. 230-235, Vol. 88.	
S	58.	LIAO, FANGZI, et al., "Is Low Magnesium Concentration a Risk Factor For Coronary Heart Disease? The Atherosclerosis Risk in Communities (ARIC) Study," Am Heart J, September 1998, pp. 480-490, Vol. 136, No. 3.	
S	59.	MARCHESONI, D., et al., "Menopause Rather than Estrogen Modifies Plasma Homocysteine Levels," International Journal of Gynecology and Obstetrics, 2003, pp. 293-297, Vol. 81.	
S	60.	MASON, JB and MILLER, J.W., "The Effects of Vitamins B12, B6, and Folate on Blood Homocysteine Levels," Ann NY Acad Sci., Sept. 30, 1992, pp. 197-203.	
S	61.	NILSSON, K., et al., "Treatment of Cobalamin Deficiency in Dementia, Evaluated Clinically and With Cerebral Blood Flow Measurements," Aging (Milano), June 2000, pp. 199-207, Vol. 12.	
S	62.	OLSZEWSKI, ANDRZEJ J., et al., "Reduction of Plasma Lipid and Homocysteine Levels by Pyridoxine, Folate, Cobalamin, Choline, Riboflavin, and Troxerutin in Atherosclerosis," Atherosclerosis, 1989, pp. 1-6, Vol. 75.	
S	63.	ROSSI, A., et al., "Early-Onset Combined Methymalonic Aciduria and Homocystinuria: Neuroradiologic Findings," Am J. Neuroradiol, March 2001, pp. 554-563, Vol. 22.	

Examiner Signature	G. Keele	Date Considered	31/18/08
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6

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First Named Inventor

Venkataraman

Group Art Unit

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↳	64.	ROSSOUW, JACQUES E., et al., "Risks and Benefits of Estrogen Plus Progestin in Healthy Postmenopausal Women" JAMA, July 17, 2002, pp. 321-333, Vol. 288, No. 3.	
↳	65.	SCHNYDER, GUIDO, et al., "Effect of Homocysteine-Lowering Therapy with Folic Acid, Vitamin B ₁₂ , and Vitamin B ₆ on Clinical Outcome After Percutaneous Coronary Intervention," JAMA, August 28, 2002, pp. 973-979, Vol. 288, No. 8.	
↳	66.	SHECHTER, MICHAEL, et al., "Oral Magnesium Supplementation Inhibits Platelet-Dependent Thrombosis in Patients With Coronary Artery Disease," Am J Cardio., July 15, 1999, pp. 152-156, Vol. 84.	
↳	67.	SHECHTER, MICHAEL, et al., "Oral Magnesium Therapy Improves Endothelial Function in Patients with Coronary Artery Disease," Circulation, November 7, 2000, pp. 2351-2358, Vol. 102.	
↳	68.	STABLER, et al., "Elevations of Serum Cystathione and Homocysteine in Vitamin B-6, Folate and Cobalamin Deficient Rats," Blood, 1994, pp. 118A, Vol 84, No. 10, Suppl. 1.	
↳	69.	STAMPER, MEIR J. and MALINOW, M. RENE, "Can Lowering Homocysteine Levels Reduce Cardiovascular Risk?" The New England Journal of Medicine, Feb. 2, 1995, pp. 328-329, Vol. 332, No. 5.	
↳	70.	STEIN, JAMES H. and MCBRIDE, PATRICK E., "Hyperhomocysteinemia and Atherosclerotic Vascular Disease," Arch Intern Med., June 22, 1998; pp. 1301-1306, Vol. 158.	
↳	71.	STEPHENS, NIGEL G., et al., "Randomised Controlled Trial of Vitamin E in Patients with Coronary Disease: Cambridge Heart Antioxidant Study (CHAOS)," The Lancet, March 23, 1996, pp. 781-786, Vol. 347.	
↳	72.	STIPANUK, MARTHA H., "Metabolism of Sulfur-Containing Amino Acids," Ann. Rev. Nutr., 1986, pp. 179-209, Vol. 6.	
↳	73.	TICE, JEFFREY A., et al., "Cost-effectiveness of Vitamin Therapy to Lower Plasma Homocysteine Levels for the Prevention of Coronary Heart Disease: Effect of Grain Fortification and Beyond," JAMA, August 22/29, 2001, pp. 936-943, Vol. 286.	

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✓	74.	UELAND, P.M. and REFSUM, H., "Plasma Homocysteine, A Risk Factor For Premature Vascular Disease. Plasma Levels in Healthy Person; During Pathologic Conditions and Drug Therapy," Nord Med., 1989, pp. 293-308, Vol. 104, No. 11. (Abstract)	
✓	75.	VALAGUSSA, F., et al., "Dietary Supplementation With N-3 Polyunsaturated Fatty Acids and Vitamin E After Myocardial Infarction: Results of the GISSI-Prevenzione Trial," The Lancet, August 7, 1999, pp. 447-455, Vol. 354.	
✓	76.	VAN DER KUY, et al., "Hydroxocobalamin, A Nitric Oxide Scavenger, In the Prophylaxis of Migraine: An Open, Pilot Study," Cephalgia Sept. 2002, pp. 513-519, Vol. 22, No. 7.,	
✓	77.	VERHAAR, MARIANNE C., et al., "Effects of Oral Folic Acid Supplementation on Endothelial Function in Familial Hypercholesterolemia," Circulation, July 27, 1999, pp. 335-338, Vol. 100.	
✓	78.	VIVANCO, N., et al., "Treatment of Anorexia Nervosa," Rev Med Chil, 1992, pp. 69-75, Vol. 120. (Abstract)	
✓	79.	WATERS, DAVID D., et al., "Effects of Hormone Replacement Therapy and Antioxidant Vitamin Supplements on Coronary Atherosclerosis in Postmenopausal Women," JAMA, November 20, 2002, pages 2432-2440, Vol 288, No. 19.	
✓	80.	YANG, CHUN-YUH, "Calcium and Magnesium in Drinking Water and Risk of Death from Cerebrovascular Disease," Stroke, 1998, pp. 411-414, Vol. 29.	

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